

REMARKS:

Status

Claims 1 to 21 are pending. Claims 1, 7, 8, 11, 17, 18, and 21 to 23 have been amended, and claims 9 and 19 have been cancelled. Claims 1, 11 and 21 are the independent claims. Reconsideration and further examination are respectfully requested.

Non-Statutory Subject Matter

Claims 1 to 20 were rejected under 35 U.S.C. § 101 as allegedly reciting non-statutory subject matter. Applicant respectfully traverses this rejection.

Applicant's understanding of the rejection is that the methods recited in claims 1 and 11 are not statutory because their "result" is

*determining a region of markers with highest scores, and do not recite tangible expression of the determination of the region of markers and/or locating a statistically significant gap in the scores ... nor any recitation of an actual [or concrete] result ....*

[Office Action p. 3, first full paragraph (emphasis added).]

Applicant submits that the Office Action is not accurate in its assignment of a "result" of the claimed methods recited in claims 1 and 11. However, in the interest of advancing the

prosecution of this case, Applicant identifies in this document where the methods recited in claims 1 and 11 recite *tangible expression of the determination of the region of markers*, and by its understanding of the rejection, requests that the Examiner allow the claimed methods in view of inclusion of that recited material.

Claim 1 (emphasis added) recites, in pertinent part

1. (Currently Amended) A method of using statistical analysis of genetic data *to determine likely genetic regions for a recessive genetic disease or trait*, comprising the steps of:

\* \* \* \*,

merging the set of scores for each marker to arrive at a first merged score for each marker, the first merged score being determined under an assumption that the marker is autozygous, and a second merged score for each marker, the second merged score being determined under an assumption that the marker is not autozygous;

first assigning to each said marker a first computed function of said first merged score and said second merged score, said first computed function indicating at least in part a statistical distinction between whether said marker is autozygous and whether said marker is not autozygous;

second assigning to each one of a plurality of sequential regions of markers a second computed function of those markers in each one particular sequential region, said second computed function being responsive to said steps of first assigning; and

*identifying at least one particular said region of markers* in response to a result of said steps of second assigning, said at least one particular region of markers having an assigned result of said computed function that is substantially at least the next-to-highest result of said computed function.

Support for the recited “first computed function” is found at least at application page 17, line 20, through page 19, line 18. Support for the recited “second computed function” is found at least at application page 19, line 20 through page 21, line 6. Support for the recited steps of

“identifying at least one particular said region of markers” is found at least at application page 13, line 22, through page 14, line 12 (since a particular region of markers is selected for sequencing, this region has been identified as a region that is one of the “*likely genetic regions for a recessive genetic disease or trait*”).

Applicant also submits that the Office Action is not accurate in its application of proper law to the claims. First, identification of a particular region of markers is indeed a “useful, tangible, or concrete result”, as tacitly admitted by the Office Action in its statement rejecting the claimed methods because they allegedly “*do not recite tangible expression of the determination of the region of markers*”. Second, using the criteria set forth in the INTERIM GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS FOR PATENT SUBJECT MATTER ELIGIBILITY (OG, Nov. 22, 2005) (“INTERIM GUIDELINES”) (§ IV (C)(2)(b)(1-3), ---

- Useful --- The claims recite methods with a practical application (*e.g.*, determining a region of markers likely to identify disease) and produces a useful result (*e.g.*, identifying at least one such region). At least this named utility is specific, substantial, and practical. INTERIM GUIDELINES § IV (C)(2)(b)(1).
- Tangible --- The claims recite methods with substantial practical application. The claims are not mere recited abstractions. “In other words, the opposite meaning of ‘tangible’ is ‘abstract’.” INTERIM GUIDELINES § IV (C)(2)(b)(2).

- Concrete --- The claims recite methods that are substantially repeatable and reproducible. They can even be performed, at least in part, by a computing device. “The opposite of ‘concrete’ is unrepeatable or unpredictable.” INTERIM GUIDELINES § IV (C)(2)(b)(3).

Moreover, statutory subject matter need not be limited to a magic formula of three words. Applicant submits that the claim is statutory if it recites a method (specifically named in 35 U.S.C. § 101) that “*is useful to the public in its current form*”, or that it has “*a significant and presently available benefit to the public.*” In re Dane K. Fisher et al., 421 F.3d 1365 (Fed. Cir. 2005). The claimed methods recite inventions that do.

#### Lack of Utility

Claims 1 to 23 were rejected under § 101 as allegedly lacking patentable utility. In this regard, the Office Action states that “[t]he Examiner reviewed the specification, but did not find such utility (*i.e.*, more cost effective sequencing) disclosed. Thus, the alleged utility is not disclosed and is not apparent.” Applicant respectfully traverses this rejection.

Applicant directs the Examiner’s attention to page 5, lines 3 to 5, of the application near the end of the Summary of the Invention section, which states the following: “Because only this limited region is sequenced, *this sequencing is far more affordable and feasible than sequencing the*

*entire genome of every member of the subject population*” (emphasis added). Furthermore, “more affordable” is equivalent to “most cost effective.”

Applicant also directs the Examiner’s attention to page 14, lines 8 to 11, and page 21, lines 11 to 14 both of which state the following: “Because only a limited region of the DNA is being sequenced, this process is much more feasible than a brute-force sequencing of the entire genome (i.e., all the DNA) for every member of the population with the disease.” While cost is not specifically mentioned in this text, “much more feasible” sequencing clearly has utility.

The Examiner also states the following: “Moreover, the alleged utility is not commensurate with the claimed invention because there is no step or other limitation in the instant claims indicative or otherwise related to “determining a region for more cost-effective sequencing.” In response, Applicant notes that claims 1, 11 and 21 recite “determining a region of markers that has a highest or next-highest run of merged scores; and sequencing the region of markers that has a highest or next-highest score.” As noted above, the specification clearly indicates that sequencing a region is “more cost effective” and “much more feasible” than sequencing an entire genome. The claims therefore are completely commensurate with the claimed utility and vice versa.

The Examiner further asserts that “it is noted that the instant method is not equivalent to a method described in the MPE and cited by applicants on p. 12 as having a ‘real world’ use because the instant method does not have a stated correlation between a recessive disease and a determined score and is not particular to a specific disease or trait being claimed and is not applicable to the general class of traits.” Applicant submits that the recited methods do indeed have an identification between *the particular identified regions of markers* (a result of at least one recited

method step) and a recessive disease. The scores determined during performance of the claimed methods are useful in finding those *particular identified regions of markers*; there is no particular requirement that any other result of the claimed methods are useful. Moreover, the invention clearly is applicable to a general class of traits, namely recessive genetic diseases.

In this regard, Applicant (again) notes that the invention is not akin to a “expressed sequence tags” (ESTs) of they type discussed in *In re Dane K. Fisher et al.*, 421 F.3d 1365 (Fed. Cir. 2005). The rejection of those tags for lacking utility was upheld. The measure of utility set forth in that case was the following:

It thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public.

The present invention most certainly has a significant and presently available benefit to the public, particularly those who suffer from recessive genetic diseases. The invention permits feasible and more cost effective sequencing of genetic material related to such disease. Without the invention or some other improvement in the art, such sequencing is impractical because it requires sequencing of an entire genome of a target population. In other words, without the invention, the first step in attempting to help people who suffer from such diseases cannot take place. With the invention, this step is eminently feasible. Both those seeking to help those people and the people themselves will be able to greatly benefit from the invention. This most certainly is a patentable utility.

In view of the foregoing, withdrawal of the § 101 rejection for alleged lack of utility is requested.

#### Section 112 Rejection

Claims 1 to 23 were rejected under § 112 for alleged indefiniteness. In particular, the Examiner indicated that the limitation of a “highest or next highest merged score” is not clear “because a range of scores and/or criteria of determining [a] ‘highest’ score is not clear, and neither the claims nor the specification defines this limitation.” Applicant respectfully traverses this rejection.

In this regard, Applicant directs the Examiner’s attention to page 19, line 20, to page 20, line 23, of the specification, which sets forth a specific mathematical technique for determining a “highest or next highest run of merged scores” as claimed. While other techniques can be used, one skilled in the art of analysis of statistical data or even of mathematics would certainly be able to implement the steps explicitly set forth in this portion of the specification.

Moreover, in the interest of advancing the prosecution of this case, Applicant has amended the noted text as shown above.

Accordingly, withdrawal of this rejection is respectfully requested.

#### Section 102 and 103 Rejections

All pending claims were rejected under 35 U.S.C. § 102 over Arbour et al., *Human Mol. Genet.*, 6(5):689-694 (1997) (Arbour), under § 102 over Kruglyak et al., *Am. J. Hum. Genet.*,

56:519-527 (1995) (Kruglyak), or under § 103 over Arbour in view of Kruglyak. Applicant respectfully traverses this rejection.

Applicant hereby withdraws all previous arguments made in this case with respect to the applied art as believed to be immaterial.

Arbour does not appear to show or suggest either the first computed function (in a preferred embodiment, a ratio of a score under an assumption that the marker is autozygous to a score under an assumption that the marker is not autozygous) or the second computed function (in a preferred embodiment, a sum of a sequential set of values of the first computed function). Rather, in Arbour, “[t]he criterion for significant linkage was considered to be a LOD score of 3.0 or greater.”

While there is a similarity between the first computed function and a LOD score (see application page 19, lines 5-6), Arbour does not appear to show or suggest any second computed function at all, nor combinations of the recited first computed function in any way. Arbour also does not appear to show any operation at all on a region of markers.

Kruglyak, which was applied against dependent claims 7, 8, 17, and 18 in a § 103 rejection, does not appear to Applicant to remedy the foregoing deficiency of Arbour.

In view of the foregoing, reconsideration and withdrawal of the § 102 and § 103 rejections are respectfully requested.

No Admission

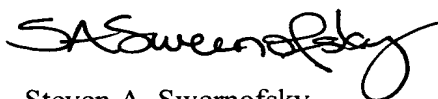
Applicant's decision not to argue each of the dependent claims separately is not an admission that the subject matter of those claims is taught by the applied art.

Closing

In view of the foregoing amendments and remarks, the entire application is believed to be in condition for allowance, and such action is respectfully requested at the Examiner's earliest convenience.

Applicant's undersigned attorney can be reached at (650) 947-0700. All correspondence should continue to be directed to the address indicated below.

Respectfully submitted,



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